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FM PTC WASHINGTON DC//ALARACT//

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\*\*\*\*\* THIS IS A COMBINED MESSAGE \*\*\*\*\*

SUBJ: ALARACT 014/2006

THIS MESSAGE HAS BEEN SENT BY THE PENTAGON TELECOMMUNICATIONS CENTER ON BEHALF OF DA WASHINGTON DC//DAMO-AOC//

SUBJ: CONTINUATION OF THE ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP) REF/A/DOC/FDA/19 DEC 05/APMN/FDA DOCKET NO. 1980-0208, BIOLOGICAL PRODUCTS; BACTERIAL VACCINES AND TOXOIDS; IMPLEMENTATION OF EFFICACY REVIEW; ANTHRAX VACCINE ADSORBED; FINAL ORDER. FEDERAL REGISTER 2005; VOLUME 70 (DEC 19). WWW.FDA.GOV/CBER/RULES/BVACTOXANTH.HTM// REF/B/MSG/HQDA/281522Z OCT 04/APMN/ALARACT MSG, SUBJ: TEMPORARILY STOP GIVING ANTHRAX IMMUNIZATIONS//

REF/C/DOC/FDA/27 JAN 05/APMN/FDA DOCKET NO. 2005N-0040, AUTHORIZATION OF EMERGENCY USE OF ANTHRAX VACCINE ADSORBED FOR PREVENTION OF INHALATION ANTHRAX BY INDIVIDUALS AT HEIGHTENED RISK OF EXPOSURE DUE TO ATTACK WITH ANTHRAX; AVAILABILITY. FEDERAL REGISTER 2005; VOLUME 70 (FEB 2): PAGES 5452-5256.

WWW.FDA.GOV/CBER/VACCINE/ANTHRAXEUA.HTM//

REF/D/DOC/USD (P&R)/29 APR 05/APMN/USD (P&R) MEMO, SUBJ: IMPLEMENTATION OF RESUMPTION OF THE ANTHRAX VACCINATION IMMUNIZATION PROGRAM UNDER EMERGENCY USE AUTHORIZATION (EUA)//

REF/E/DOC/USD (P&R)/6 AUG 02//APMN/USD (P&R) MEMO, SUBJ: POLICY ON ADMINISTRATIVE ISSUES RELATED TO THE ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP)//

REF/F/DOC/ASD (HA)/6 AUG 02//APMN/ASD (HA) MEMO, SUBJ: POLICY ON CLINICAL ISSUES RELATED TO ANTHRAX VACCINATION//

REF/G/DOC/ASD (FMP)/25 JUNE 01/APMN/ASD (FMP) MEMO, SUBJ: NOTIFYING EMERGENCY-ESSENTIAL EMPLOYEES REGARDING ANTHRAX IMMUNIZATION REQUIREMENTS//

1. (U) ON 19 DEC 05, OFFICIALS FROM THE FOOD AND DRUG ADMINISTRATION (FDA) ISSUED A FINAL ORDER (REF A), FINDING THAT ANTHRAX VACCINE PROTECTS AGAINST ALL ROUTES OF EXPOSURE TO ANTHRAX SPORES, INCLUDING INHALATION. AFTER EVALUATION OF THE FULL SCIENTIFIC LITERATURE AND ASSESSING COMMENTS FROM THE PUBLIC SUBMITTED IN EARLY 2005, THE FDA REAFFIRMED ITS PREVIOUS CONCLUSIONS. BECAUSE THIS REGULATORY ACTION REMOVED THE BASIS AND NEED FOR THE EMERGENCY USE AUTHORIZATION (EUA) DOD HAS FOLLOWED SINCE APRIL 2005, IT WILL NOT BE NECESSARY FOR DOD TO SEEK RENEWAL OF THE EUA FOR USE OF ANTHRAX VACCINE TO PREVENT INHALATION ANTHRAX. THE EUA EXPIRES JANUARY 14, 2006. WHILE OUR SENIOR CIVILIAN LEADERS COMPLETE A POLICY REVIEW, DOD WILL CONTINUE VOLUNTARY ANTHRAX VACCINATIONS FOR THE SAME PEOPLE ELIGIBLE UNDER THE EUA. THIS INTERIM APPROACH WILL CONTINUE TO INCLUDE EDUCATIONAL BRIEFINGS, AND AN OPTION TO REFUSE. PERSONNEL REFUSING VACCINATION WILL NOT BE PUNISHED. NO DISCIPLINARY ACTION OR ADVERSE PERSONNEL ACTION WILL BE TAKEN. PERSONNEL WILL NOT BE PROCESSED FOR SEPARATION AND THERE WILL NOT BE A PENALTY OR LOSS OF ENTITLEMENT FOR REFUSING THE ANTHRAX VACCINATION. PERSONNEL WHO REFUSE ANTHRAX VACCINATION REMAIN DEPLOYABLE.

2. (U) BACKGROUND: ON 27 OCT 04, THE US DISTRICT COURT FOR THE DISTRICT OF COLUMBIA PLACED AN INJUNCTION ON MANDATORY ANTHRAX

VACCINATIONS (REF B). ON 10 DEC 04, THE DEPUTY SECRETARY OF DEFENSE DETERMINED THAT THERE IS A SIGNIFICANT POTENTIAL FOR A MILITARY EMERGENCY INVOLVING UNITED STATES MILITARY FORCES AND AN ATTACK WITH ANTHRAX. SINCE APR 05, THE AVIP HAS BEEN CONDUCTED UNDER AN EUA ISSUED BY THE FDA (REF C AND D). CORE IMPLEMENTATION INSTRUCTIONS APPEAR IN REFS E, F, AND G.

3. (U) PERSONNEL ELIGIBLE FOR ANTHRAX VACCINATION.

3.A. (U) GENERAL. AT THIS TIME, MAJOR COMMANDS (MACOMS) ARE DIRECTED TO CONTINUE VOLUNTARY ANTHRAX VACCINATIONS FOR PERSONNEL ON ORDERS TO LOCATIONS OR ASSIGNED ROLES DETAILED BELOW AND MAY BEGIN UP TO 60 DAYS BEFORE DEPARTURE.

3.B. (U) MILITARY PERSONNEL. THE AVIP EUA PROCEDURES WILL REMAIN IN EFFECT FOR MILITARY PERSONNEL SERVING IN US CENTRAL COMMAND (USCENTCOM) AREA OF RESPONSIBILITY (AOR) OR US FORCES KOREA (USFK) FOR 15 OR MORE CONSECUTIVE DAYS, DESIGNATED SPECIAL-MISSION UNITS, DESIGNATED UNITS WITH BIOWARFARE- OR BIOTERRORISM-RELATED MISSIONS, AND OTHER UNITS EXPLICITLY DESIGNATED BY THE UNDER SECRETARY OF DEFENSE (PERSONNEL & READINESS). CENTCOM HEADQUARTERS MAY PROVIDE ADDITIONAL INSTRUCTIONS CONSISTENT WITH THIS MESSAGE FOR ALL COMPONENT MEDICAL TREATMENT FACILITIES WITHIN THE CENTCOM AOR.

3.C. (U) CIVILIAN EMPLOYEES. AFTER ENSURING STATUTORY AND CONTRACTUAL LOCAL LABOR RELATIONS OBLIGATIONS HAVE BEEN MET, UNIT LEADERS WILL PROACTIVELY OFFER ANTHRAX VACCINATION TO EMERGENCY-ESSENTIAL AND EQUIVALENT DOD CIVILIAN EMPLOYEES 18 TO 65 YEARS OLD SERVING IN USCENTCOM AOR OR US FORCES KOREA FOR 15 OR MORE CONSECUTIVE DAYS OR OTHER DESIGNATED UNITS. CONTACT LOCAL CIVILIAN PERSONNEL ADVISORY CENTERS FOR GUIDANCE ON MEETING LABOR-RELATIONS OBLIGATIONS. EQUIVALENT CIVILIAN EMPLOYEES MEANS DOD EMPLOYEES WHOSE DUTIES MEET ALL THE REQUIREMENTS OF 10 USC 1580, BUT WHO HAVE NOT BEEN DESIGNATED AS EMERGENCY-ESSENTIAL. OTHER DOD CIVILIAN EMPLOYEES SERVING IN THESE AREAS FOR 15 OR MORE CONSECUTIVE DAYS MAY ALSO ACCEPT AND RECEIVE ANTHRAX VACCINATION.

3.D. (U) CONTRACTED WORKERS. VACCINATIONS AND RELATED MEDICAL CARE SHALL BE SPECIFIED IN RELEVANT CONTRACTS. UNIT LEADERS WILL PROACTIVELY OFFER ANTHRAX VACCINATION TO MISSION-ESSENTIAL CONTRACTED WORKERS SERVING IN USCENTCOM AOR OR US FORCES KOREA FOR 15 OR MORE CONSECUTIVE DAYS OR OTHER DESIGNATED UNITS.

3.E. (U) OTHERS. ADULT FAMILY MEMBERS (18 TO 65 YEARS OLD) OF CATEGORIES ABOVE WHO RESIDE IN USCENTCOM AOR OR WITH US FORCES KOREA AND OTHER DOD-CONTRACTED WORKERS WHO ARE US CITIZENS SERVING IN USCENTCOM AOR OR US FORCES KOREA FOR 15 OR MORE CONSECUTIVE DAYS MAY ALSO ACCEPT AND RECEIVE ANTHRAX VACCINATION.

4. (U) ISSUES UNIQUE TO THE RESERVE COMPONENTS (RC):

4.A. (U) MOST SOLDIERS BEING MOBILIZED FOR DEPLOYMENT TO A HIGH-THREAT AREA REQUIRING ANTHRAX VACCINATION WILL BE OFFERED INITIAL AND SUBSEQUENT DOSES AFTER ARRIVING AT THE MOBILIZATION STATION. SOLDIERS WHO HAVE DEMOBILIZED OR WHO HAVE PREVIOUSLY RECEIVED ANTHRAX VACCINATION WILL NOT CONTINUE THE DOSING SERIES. IN CASES WHERE RC SOLDIERS WILL BE IN A HIGH-THREAT AREA FOR 15 DAYS OR MORE (EXCLUDING TRAVEL TIME) ON ANNUAL TRAINING OR OTHER DUTY ORDERS, UNITS WILL COORDINATE FOR TIMELY VACCINATION OF THESE SOLDIERS THROUGH THEIR CHAIN OF COMMAND TO THE ARMY RESERVE SURGEONS OFFICE.

4.B. (U) PERSONNEL SHALL BE IN A DUTY STATUS WHEN RECEIVING ANY DOD-DIRECTED IMMUNIZATION. UNIT COMMANDERS MUST ENSURE PERSONNEL TO RECEIVE ANTHRAX VACCINATION ARE ELIGIBLE AND ARE IN A DUTY STATUS.

4.C. (U) RESERVE COMPONENT MEMBERS WHO INCUR OR AGGRAVATE ANY INJURY, ILLNESS, OR DISEASE WHILE PERFORMING ACTIVE DUTY FOR LESS THAN 30

DAYS, OR ON INACTIVE DUTY TRAINING STATUS ARE ENTITLED TO MEDICAL CARE APPROPRIATE FOR THE TREATMENT OF THE INJURY, ILLNESS OR DISEASE.

\*\*\*\*\* START OF SECTION 2 \*\*\*\*\*

AN ADVERSE REACTION FROM A DOD-DIRECTED IMMUNIZATION IS A LINE OF DUTY CONDITION. THEREFORE, WHEN A MEMBER OF THE RC PRESENTS FOR TREATMENT AT A MILITARY TREATMENT FACILITY (MTF), EXPRESSING A BELIEF THAT THE CONDITION FOR WHICH TREATMENT IS SOUGHT IS RELATED TO RECEIVING AN IMMUNIZATION DURING A PERIOD OF DUTY, THE MEMBER MUST BE EXAMINED AND PROVIDED NECESSARY MEDICAL CARE.

4.D. (U) WHEN TREATMENT HAS BEEN RENDERED OR THE INDIVIDUAL'S EMERGENT CONDITION IS STABILIZED, A LINE OF DUTY AND/OR NOTICE OF ELIGIBILITY WILL BE DETERMINED AS SOON AS POSSIBLE. FOR INJURIES, ILLNESS OR DISEASE UNRELATED TO DUTY, RC MEMBERS SHOULD SEEK MEDICAL ATTENTION FROM THEIR PERSONAL HEALTHCARE PROVIDERS.

5. (U) THE AVIP REMAINS A COMMANDERS RESPONSIBILITY TO ENHANCE TROOPS FORCE PROTECTION. AS A REMINDER, THE FDA-APPROVED SCHEDULE FOR ANTHRAX VACCINE IS A 6-DOSE SERIES: 0, 2, AND 4 WEEKS; THEN 6, 12, AND 18 MONTHS, FOLLOWED BY ANNUAL BOOSTERS. COMMANDERS SHOULD TAKE THE FOLLOWING PROACTIVE STEPS:

5.A. (U) ENSURE ARMY LEADERS (OFFICERS, NCOS, AND CIVILIAN SUPERVISORS) ARE FAMILIAR WITH THE REVISED AVIP POLICY.

5.B. (U) ENSURE ARMY LEADERS BECOME FAMILIAR NOW WITH RESOURCES AT THE DOD WEBSITE WWW.ANTHRAX.MIL. EXPERIENCE SHOWS THAT EDUCATION IS PIVOTAL TO AVIP SUCCESS AND ACCEPTABILITY. A GOOD FIRST STEP IS TO REVIEW THE COMMANDERS TOOLKIT AND THE QUESTIONS AND ANSWERS POSTED ON THE WEBSITE. THESE ARE THE QUESTIONS MOST FREQUENTLY ASKED BY TROOPS, EMPLOYEES AND THEIR FAMILIES. MEDICAL PERSONNEL SHOULD LIKEWISE BECOME FAMILIAR NOW WITH RESOURCES AT THE DOD WEBSITE, PARTICULARLY THE CLINICIANS TOOLKIT.

5.C. (U) ENSURE MEDICAL PERSONNEL UNDERSTAND THE POTENTIAL ADVERSE EVENTS AFTER VACCINATION--HOW TO MINIMIZE THEM, RESPOND TO THEM, AND REPORT THEM TO THE FDAS VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) AT WWW.VAERS.HHS.GOV AND IAW AR 40-562. MEDICAL PERSONNEL WILL NOT ONLY ADMINISTER THE VACCINE, BUT MUST BE READY TO RESPOND TO TROOPS AND EMPLOYEES QUESTIONS AND CONCERNS. TREAT EACH CONCERN WITH CARE--SYMPTOMS AFTER VACCINATION MAY OR MAY NOT BE CAUSED BY THE VACCINATION, BUT ALL PERSONNEL DESERVE INDIVIDUAL ATTENTION.

5.D. (U) DISTRIBUTE THE CURRENT AVIP TRIFOLD BROCHURE (DATED 16 DEC 05) TO ALL PERSONNEL RECEIVING THE ANTHRAX BRIEFING BEFORE THEIR DECISION TO ACCEPT OR DECLINE THE VACCINE. CONTINUE TO TRACK PERSONNEL RECEIVING THE TRIFOLD ON ROSTERS MAINTAINED AT THE UNIT LEVEL. UPDATED TRIFOLDS ARE SHIPPED WITH VACCINE ORDERS OR ARE AVAILABLE FOR DOWNLOADING AND LOCAL PRINTING FROM THE WWW.ANTHRAX.MIL WEBSITE. TO ORDER ADDITIONAL TRIFOLD BROCHURES, SEND AN EMAIL MESSAGE TO USAMMADOC@DET.AMEDD.ARMY.MIL (MENTION DESIRED SHIPPING ADDRESS AND RELATED DETAILS).

6. (U) IMMUNIZATION TRACKING IS ESSENTIAL FOR COMPLETE HEALTH RECORDS. ENSURE ALL UNIT IMMUNIZATIONS ARE POSTED AND TRACKED IN THE MEDICAL PROTECTION SYSTEM (MEDPROS), THE HQDA STANDARD FOR TRACKING ALL INDIVIDUAL MEDICAL READINESS INDICATORS IN THE ACTIVE AND RESERVE COMPONENTS. ENSURE YOUR UNIT HAS SUFFICIENT MEDICAL AND NON-MEDICAL PERSONNEL TRAINED IN THE MEDPROS IMMUNIZATION-TRACKING SOFTWARE APPLICATION WITH CURRENT PASSWORD ACCESS TO THE SYSTEM. LEADERS AT ALL LEVELS CAN TRACK INDIVIDUAL AND UNIT COMPLIANCE USING MEDPROS, A MODERN, EASY-TO-USE, WEB-BASED TRACKING SYSTEM, ACCESSED AT WWW.MODS.ARMY.MIL. INDIVIDUALS CAN PRINT OUT THEIR PERSONAL ELECTRONIC IMMUNIZATION RECORD VIA ARMY KNOWLEDGE ONLINE AT ITS MY

MEDICAL READINESS SECTION.

7. (U) THE U.S. ARMY MEDICAL MATERIEL AGENCY (USAMMA) WILL COORDINATE THE DISTRIBUTION OF ANTHRAX VACCINE TO THE SUPPORTING MEDICAL SUPPLY ACTIVITIES OF ALL SERVICES. LOCAL MEDICAL LOGISTICS SUPPORTING ELEMENTS MUST HAVE SUFFICIENT REFRIGERATION CAPACITY TO PRESERVE VACCINE INTEGRITY, INCLUDING TEMPERATURE ALARMS AND BACK-UP POWER CAPACITY. END-USERS WILL DIRECTLY REQUISITION VACCINE IAW USAMMA GUIDELINES IN THE ARMY IMPLEMENTATION PLAN. POCS AT USAMMA: (1) USAMMA DISTRIBUTION OPERATIONS CENTER COMM: 301-619-4318/4307/4198, DSN: 343-XXXX, FAX: DSN 343-4468. (2) WEBSITE: WWW.USAMMA.ARMY.MIL AND THEN CLICK ON VACCINES/TEMPERATURE SENSITIVE PRODUCTS. (3) EMAIL: USAMMADOC@DET.AMEDD.ARMY.MIL.

8. (U) POCS FOR THIS MESSAGE ARE COL JOHN GRABENSTEIN OR LTC RANDALL ANDERSON AT 703-681-5101 OR DSN 761-5101, OR EMAIL: VACCINES@AMEDD.ARMY.MIL OR OTSG.OPSCENTER21OPNS@HQDA-S.ARMY.SMIL.MIL (ATTENTION: MILVAX).

9. EXPIRATION DATE CANNOT BE DETERMINED.

BT